

Declaration of Conformity

Technical File Reference: DD-010

Issuer's Name: Grifols Diagnostic Solutions Inc.
Issuer's Contact Information: 4560 Horton Street
 Emeryville, CA 94608, USA

Authorized Representative: Diagnostic Grifols, S.A.
 Passeig Fluvial, 24
 08150 Parets del Vallès, Spain

Object of the Declaration:

Catalog No.	Description
303330 / 303715	Procleix® Ultrio Elite® Assay
303334	Procleix® Ultrio Elite® HIV, HCV, and HBV Discriminatory Probe Reagents
303331 / 303722	Procleix® Ultrio Elite® Target Enhancer Reagent
303333	Procleix® Ultrio Elite® Negative Calibrators
303332	Procleix® Ultrio Elite® Positive Calibrators
303719 / 303723	Procleix® Ultrio Elite® Assay Calibrators Kit

Grifols Diagnostic Solutions Inc. declares that the above mentioned object of the declaration meets the provision of the Council Directive 98/79/EC for the In Vitro Diagnostic Medical Devices and the IVDD Directive 98/79/EC as transposed in the national laws of the Member States.

The object of the declaration described above is in conformity with the requirements of the following standards:

Standard	Revision	Title
EN ISO 13485	2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
EN 13612	2002	Performance evaluation of <i>in-vitro</i> diagnostic medical devices
EN 13975	2003	Sampling procedures used for acceptance testing of <i>in vitro</i> diagnostic medical devices – Statistical aspects
EN ISO 14971	2012	Medical devices – Application of risk management to medical devices – Rationale for requirements
EN ISO 15223-1	2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 18113-1 EN ISO 18113-2	2011	<i>In Vitro</i> Diagnostic Medical Devices – Information Supplied by the Manufacturer. Part 1: Terms, definitions and general requirements. (Part 2: IVD Reagents for Professional Use)
ISO 23640	2015	<i>In Vitro</i> diagnostic medical devices – Evaluation of stability of <i>in vitro</i> diagnostic reagents

GRIFOLS

Additional Information:

Classification/

Conformity Assessment:

Notified Body:

Certificate Number:

Date of Current CE Mark:

Annex II, List A/ Annex IV, Section 4

Polish Centre for Testing and Certification (PCBC) (1434)

1434-IVDD-222/2019

26 April 2019

Signed for and on behalf of: Grifols Diagnostic Solutions Inc.



26 Apr 2019

Amanda Doe, Manager, Regulatory Affairs

Date